



Practitioner's Docket No. 55965 (46342)

PATENT

1647  
#11B  
3/11/03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: T. Ito, et al.  
Application No.: 09/857,815 Group No.: 1647  
Filed: June 8, 2001 Examiner: Deberry, Regina M.  
For: BETACELLULIN MUTEIN

Box Sequence  
Assistant Commissioner for Patents  
Washington, D.C. 20231

RECEIVED  
MAR 04 2003  
TECH CENTER 1600/2900

SUBMISSION OF "SEQUENCE LISTING," COMPUTER READABLE COPY,  
AND/OR AMENDMENT PERTAINING THERETO  
FOR BIOTECHNOLOGY INVENTION CONTAINING NUCLEOTIDE  
AND/OR AMINO ACID SEQUENCE

(check and complete this item, if applicable)

CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10\*

(When using Express Mail, the Express Mail label number is **mandatory**;  
Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

MAILING

☒ deposited with the United States Postal Service in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

37 C.F.R. SECTION 1.8(a)

37 C.F.R. SECTION 1.10\*

☒ with sufficient postage as first class mail.

☐ as "Express Mail Post Office to Address"  
Mailing Label No. \_\_\_\_\_ (mandatory)

TRANSMISSION

☐ transmitted by facsimile to the Patent and Trademark Office (703) \_\_\_\_ - \_\_\_\_.

Date: February 21, 2003

Signature

Eileen M Woodbury  
Eileen M. Woodbury

**\*WARNING:** Each paper or fee filed by "Express Mail" **must** have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. Section 1.10(b).  
"Since the filing of correspondence under section 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442. (Submission-Nucleotide

1. ☒ This replies to the Office Letter DATED January 21, 2003

NOTE: If these papers are filed before the office letter issues, adequate identification of the original papers should be made, e.g., in addition to the name of the inventor and title of invention, the filing date based on the "Express Mail" procedure, the application number from the return post card or the attorney's docket number added.

☒ A copy of the Office Letter is enclosed.

#### IDENTIFICATION OF PERSON MAKING STATEMENT

2. I, Cara Z. Lowen  
(type or print name of person signing below)

state the following:

RECEIVED  
MAR 04 2003  
TECH CENTER 1600/2900

#### ITEMS BEING SUBMITTED

3. Submitted herewith is/are:

(check each item as applicable)

- A. ☒ "Sequence Listing(s)" for the nucleotide and/or amino acid sequence(s) in this application. Each "Sequence Listing" is assigned a separate identifier as required in 37 C.F.R. Section 1.821(c) and 37 C.F.R. Sections 1.822 and 1.823.
- B. ☒ An amendment to the description and/or claims, wherein reference is made to the sequence by use of the assigned identifier, as required in 37 C.F.R. Section 1.821(d).
- C. ☒ A copy of each "Sequence Listing" submitted for this application in computer readable form, in accordance with the requirements of 37 C.F.R. Sections 1.821(e) and 1.824.
- D. ☐ Please transfer to this application, in accordance with 37 C.F.R. Section 1.821(e), the computer readable copy(ies) from applicant's other application identified as follows:

In re application of:  
Application No.: 0 /  
Filed:  
For:

Group No.:  
Examiner:

The Computer readable form(s) of applicant's other application corresponds to the "Sequence Identifier(s)" of the application as follows:

Computer Readable Form  
(other application)

"Sequence Identifier"  
(this application)

*NOTE: "If the computer readable form of a new application is to be identical with the computer readable form of another application of the applicant on file in the Office, reference maybe made to the other application and computer readable form in lieu of filing a duplicate computer readable form in the new application. The new application shall be accompanied by a letter making such reference to the other application and computer readable form, both of which shall be completely identified." 37 C.F.R. Section 1.821(e).*

E. ☒ A statement that the content of each "Sequence Listing" submitted and each computer readable copy are the same, as required in 37 C.F.R. Section 1.821(g).

☐ Because the statement is not made by a person registered to practice before the Office, the Statement is verified as required in 37 C.F.R. Section 1.821(b).

F. ☒ Because this submission is made in fulfilling the requirement under 37 C.F.R. Section 1.821(g), a statement that the submission includes no new matter.

☐ Because the statement is not made by a person registered to practice before the Office, the statement is verified, as required in 37 C.F.R. Section 1.821(g).

**STATEMENT THAT "SEQUENCE LISTING"  
AND COMPUTER READABLE COPY ARE THE SAME  
AND/OR THAT PAPERS SUBMITTED INCLUDES NO NEW MATTER**

4. I hereby state:

*(complete applicable item A and/or B)*

A. ☒ Each computer readable form submitted in this application, including those forms requested to be transferred from applicant's other application, is the same as the "Sequence Listing" to which it is indicated to relate.

B. ☒ All papers accompanying this submission, or for which a request for transfer from applicants' other application, introduce no new matter.

## STATUS

5. Applicant is

☐ a small entity. A statement:

☐ is attached.

☐ was already filed.

☒ other than a small entity.

## EXTENSION OF TERM

6.

*NOTE: "Extension of Time in Patent Cases (Supplement Amendments) If a timely and complete response has been filed after a Non-Final Office Action, an extension of time is not required to permit filing and/or entry of an additional amendment after expiration of the shortened statutory period.*

*If a timely response has been filed after a Final Office Action, an extension of time is required to permit filing and/or entry of a Notice of Appeal or filing and/or entry of an additional amendment after expiration of the shortened statutory period unless the timely-filed response placed the application in condition for allowance. Of course, if a Notice of Appeal has been filed within the shortened statutory period, the period has ceased to run." Notice of Dec.10, 1985 (1061 O.G. 34-35).*

*NOTE: See 37 C.F.R. Section 1.645 for extensions of time in interference proceedings and 37 C.F.R. Section 1.550(c) for extensions of time in reexamination proceedings.*

7. The proceedings herein are for a patent application and the provisions of 37 C.F.R. Section 1.136 apply.

*(complete (a) or (b) as applicable)*

(a) ☐ Applicant petitions for an extension of time under 37 C.F.R. Section 1.136 (fees: 37 C.F.R. Section 1.17(a)(1)-(4)) for the total number of months checked below:

<u>Extension</u> <u>(months)</u>	<u>Fee for other than</u> <u>small entity</u>	<u>Fee for</u> <u>small entity</u>
<input type="checkbox"/> one month	\$ 110.00	\$ 55.00
<input type="checkbox"/> two months	\$ 410.00	\$ 205.00
<input type="checkbox"/> three months	\$ 930.00	\$ 465.00
<input type="checkbox"/> four months	\$1,450.00	\$ 725.00

Fee \$ \_\_\_\_\_

If an additional extension of time is required, please consider this a petition therefor.

(check and complete the next item, if applicable)

- ☐ An extension for \_\_\_\_\_ months has already been secured, and the fee paid therefor of \$ \_\_\_\_\_ is deducted from the total fee due for the total months of extension now requested.

Extension fee due with this request \$ \_\_\_\_\_

OR

- (b) ☒ Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

**FEE PAYMENT**

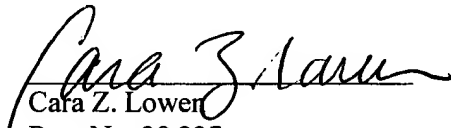
8. ☐ Attached is a check in the sum of \$ \_\_\_\_\_.
- ☐ Charge Account No. \_\_\_\_\_ the sum of \$ \_\_\_\_\_.
- A duplicate of this transmittal is attached.

**FEE DEFICIENCY**

9.

*NOTE: If there is a fee deficiency and there is no authorization to charge an account, additional fees are necessary to cover the additional time consumed in making up the original deficiency. If the maximum, six-month period has expired before the deficiency is noted and corrected, the application is held abandoned. In those instances where authorization to charge is included, processing delays are encountered in returning the papers to the PTO finance Branch in order to apply these charges prior to action on the cases. Authorization to charge the deposit account for any fee deficiency should be checked. See the Notice of April 7, 1986, 1065 O.G. 31-33.*

10. ☒ If any additional extension and/or fee is required, charge Account No. 04-1105.

  
Cara Z. Lower  
Reg. No. 38,227

Dike, Bronstein, Roberts & Cushman  
Intellectual Property Group of  
EDWARDS & ANGELL, LLP  
P.O. Box 9169  
Boston, MA 02209  
(617) 517-5509

Date: February 21, 2003

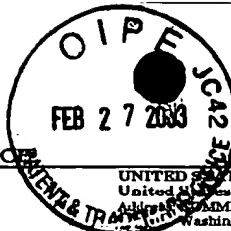
Customer No. 21,874

RECEIVED  
MAR 04 2003  
TECH CENTER 1600/2900

76C1C2L 55965(46342)



UNITED STATES PATENT AND TRADEMARK OFFICE



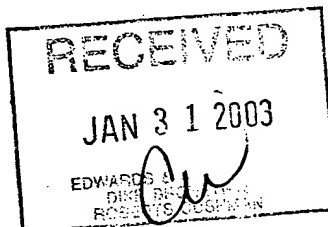
UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,815	06/08/2001	Takashi Ito	46342/55965	9695

7590

01/22/2003

DIKE, BRONSTEIN, ROBERTS AND CUSHMAN  
EDWARDS AND ANGELL  
P.O. BOX 9169  
BOSTON, MA 02209



EXAMINER

DEBERRY, REGINA M

ART UNIT PAPER NUMBER

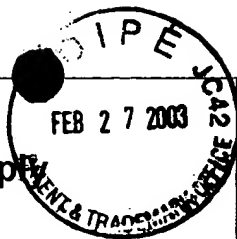
1647

DATE MAILED: 01/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

COPY

Sequence Listing Due  
Edwards & Angell LLP  
Dike, Bronstein, Roberts & Cushman  
101 Federal St. Boston, MA 02110  
Date Rec'd 1/21/03  
Docketed For 2/21/03 - 02/21/03  
By [Signature]  
Approved



## Notice to Comply

Application No.

09/857,815

Examiner

Regina M. DeBerry

Applicant(s)

ITO ET AL.

Art Unit

1647

### NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☒ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked-up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☒ 7. Other: The instant application fails to fully comply with the sequence rules 37 CFR 1.821-1.825 because each disclosure of a sequence embraced by the definitions set forth in the rules fails to refer to the required sequence identifier (SEQ ID NO:). This occurs on pages 14-17, 24, 64, 68, 81, 85, 89, 101, 102, 109, 110, and 113 of the instant specification. The specification should be checked for missing SEQ ID Nos.

#### Applicant Must Provide:

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

PatentIn Software Program Support

Technical Assistance.....703-287-0200

To Purchase PatentIn Software.....703-306-2600

**PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY**



## UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, DC 20231  
www.uspto.gov

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
---------------------------------	-------------	---	---------------------



EXAMINER
----------

ART UNIT	PAPER
----------	-------

15

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

## Commissioner of Patents

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

APPLICANT IS GIVEN 30 days FROM THE DATE OF THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.F.R. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Regina M. DeBerry**, whose telephone number is (703) 305-6915. The examiner can normally be reached on **Mondays-Fridays 8:00 a.m.-4:30 p.m.**

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz** can be reached at (703) 308-4623. The fax number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

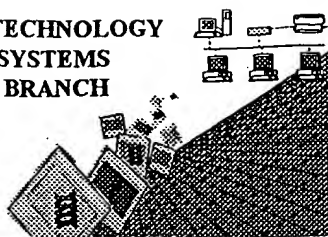
ELIZABETH KEMMERER  
PRIMARY EXAMINER



R. Leberry  
10008



BIOTECHNOLOGY  
SYSTEMS  
BRANCH



## RAW SEQUENCE LISTING ERROR REPORT

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number: 09/857,815A  
Source: 1600  
Date Processed by STIC: 3/18/2002

THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.

PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:

- 1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,
- 2) TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY

FOR CRF SUBMISSION QUESTIONS, PLEASE CONTACT MARK SPENCER, 703-308-4212.

FOR SEQUENCE RULES INTERPRETATION, PLEASE CONTACT ROBERT WAX, 703-308-4216.

PATENTIN 2.1 e-mail help: [patin21help@uspto.gov](mailto:patin21help@uspto.gov) or phone 703-306-4119 (R. Wax)

PATENTIN 3.0 e-mail help: [patin3help@uspto.gov](mailto:patin3help@uspto.gov) or phone 703-306-4119 (R. Wax)

TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE CHECKER  
VERSION 3.1 PROGRAM, ACCESSIBLE THROUGH THE U.S. PATENT AND  
TRADEMARK OFFICE WEBSITE. SEE BELOW FOR ADDRESS:

<http://www.uspto.gov/web/offices/pac/checker>

Applicants submitting genetic sequence information electronically on diskette or CD-Rom should be aware that there is a possibility that the disk/CD-Rom may have been affected by treatment given to all incoming mail.

Please consider using alternate methods of submission for the disk/CD-Rom or replacement disk/CD-Rom.

Any reply including a sequence listing in electronic form should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office, and instead should be sent via the following to the indicated addresses:

1. EFS-Bio (<<http://www.uspto.gov/ebc/efs/downloads/documents.htm>> , EFS Submission User Manual - ePAVE)
2. U.S. Postal Service: U.S. Patent and Trademark Office, Box Sequence, P.O. Box 2327, Arlington, VA 22202
3. Hand Carry directly to:  
U.S. Patent and Trademark Office, Technology Center 1600, Reception Area, 7<sup>th</sup> Floor, Examiner Name, Sequence Information, Crystal Mall One, 1911 South Clark Street, Arlington, VA 22202  
Or  
U.S. Patent and Trademark Office, Box Sequence, Customer Window, Lobby, Room 1B03, Crystal Plaza Two, 2011 South Clark Place, Arlington, VA 22202
4. Federal Express, United Parcel Service, or other delivery service to: U.S. Patent and Trademark Office, Box Sequence, Room 1B03-Mailroom, Crystal Plaza Two, 2011 South Clark Place, Arlington, VA 22202



1600

## RAW SEQUENCE LISTING

PATENT APPLICATION: US/09/857,815A

DATE: 12/11/2002

TIME: 14:19:09

Input Set : A:\SEQ01044rev2.txt

Output Set: N:\CRF4\12112002\I857815A.raw

C--> 9 <110> APPLICANT: Takeda Chemical Industries, Ltd.  
5 <120> TITLE OF INVENTION: Betacellulin Mutein  
7 <130> FILE REFERENCE: P2001-232  
C--> 9 <140> CURRENT APPLICATION NUMBER: US/09/857,815A  
C--> 9 <141> CURRENT FILING DATE: 2001-06-08  
9 <150> PRIOR APPLICATION NUMBER: JP 10-350377  
10 <151> PRIOR FILING DATE: 1998-12-09  
12 <150> PRIOR APPLICATION NUMBER: JP 11-55326  
13 <151> PRIOR FILING DATE: 1999-03-03  
15 <160> NUMBER OF SEQ ID NOS: 56  
17 <210> SEQ ID NO: 1  
18 <211> LENGTH: 77  
19 <212> TYPE: PRT  
20 <213> ORGANISM: Human  
22 <400> SEQUENCE: 1  
23 Asp Gly Asn Ser Thr Arg Ser Pro Glu Thr Asn Gly Leu Leu Cys Gly  
24 1 5 10 15  
25 Asp Pro Glu Glu Asn Cys Ala Ala Thr Thr Thr Gln Ser Lys Arg Lys  
26 20 25 30  
27 Gly His Phe Ser Arg Cys Pro Lys Gln Tyr Lys His Tyr Cys Ile Lys  
28 35 40 45  
29 Gly Arg Cys Arg Phe Val Val Ala Glu Gln Thr Pro Ser Cys Val Cys  
30 50 55 60  
31 Asp Glu Gly Tyr Ile Gly Ala Arg Cys Glu Arg Val Asp  
32 65 70 75  
34 <210> SEQ ID NO: 2  
35 <211> LENGTH: 76  
36 <212> TYPE: PRT  
37 <213> ORGANISM: Human  
39 <400> SEQUENCE: 2  
40 Asp Gly Asn Ser Thr Arg Ser Pro Glu Thr Asn Gly Leu Leu Cys Gly  
41 1 5 10 15  
42 Asp Pro Glu Glu Asn Cys Ala Ala Thr Thr Thr Gln Ser Lys Arg Lys  
43 20 25 30  
44 Gly His Phe Ser Arg Cys Pro Lys Gln Tyr Lys His Tyr Cys Ile Lys  
45 35 40 45  
46 Gly Arg Cys Arg Phe Val Val Ala Glu Gln Thr Pro Ser Cys Val Cys  
47 50 55 60  
48 Asp Glu Gly Tyr Ile Gly Ala Arg Cys Glu Arg Val  
49 65 70 75  
51 <210> SEQ ID NO: 3  
52 <211> LENGTH: 47  
53 <212> TYPE: PRT

Does Not Comply  
Corrected Diskette Needed

see p. 2

1/857/0651  
insert this mandatory numeric identifier  
and response

<210> 37

<211> 75

<213> Human

><2127 PRT

invalid

<400> 37

Gly Asn Ser Thr Arg Ser Pto Glu Thr Asn Gly Leu Leu Cys Gly Asp  
1 5 10 15  
Pro Glu Glu Asn Cys Ala Ala Thr Thr Thr Gln Ser Lys Arg Lys Gly  
20 25 30  
His Phe Ser Arg Cys Pro Lys Gln Tyr Lys His Tyr Cys Ile Lys Gly  
35 40 45  
Arg Cys Arg Phe Val Val Ala Glu Gln Thr Pro Ser Cys Val Cys Asp  
50 55 60  
Glu Gly Tyr Ile Gly Ala Arg Cys Glu Arg Val  
65 70 75

<210> 38

<211> 53

<213> Human

><2127 PRT

same error

<400> 38

Ala Thr Thr Thr Gln Ser Lys Arg Lys Gly His Phe Ser Arg Cys Pro  
1 5 10 15  
Lys Gln Tyr Lys His Tyr Cys Ile Lys Gly Arg Cys Arg Phe Val Val  
20 25 30  
Ala Glu Gln Thr Pro Ser Cys Val Cys Asp Glu Gly Tyr Ile Gly Ala  
35 40 45  
Arg Cys Glu Arg Val  
50 53